

REMARKS

The office action issued by the Examiner and the citations referred to in the office action have been carefully considered.

Objections To The Specification

One page 3 of the Office Action, the Examiner objects to "IMAC" and "HP" indicating that they should be spelled out in full for the first instance of use. Applicants note that "IMAC HP 1110Na" is the trade name used by the manufacturer, Rohm & Haas Inc., USA, for the resin identified. Applicants do not know the full name and were not able find the full name after reasonable inquiry.

In response, Applicants have amended the specification to replace "IMAC HP 1110Na" with, "resin IMAC HP 1110Na, from Rohm & Haas Inc., USA" to more clearly identify the resin indicated. Accordingly, Applicants respectfully request that the Examiner withdraw his objection to the specification.

Objections To Pending Claim 6

On page 3 of the Office Action, the Examiner also objects to claim 6 indicating "a cut off" should be changed to "a molecular weight cut-off." In response, Applicants have amended claim 6 as requested by the Examiner. Accordingly, Applicants respectfully request that the Examiner withdraw his objection to the claim 6.

Rejection of Claims 1-10 Under 35 U.S.C. §112, Second Paragraph

One page 2 of the Office Action, the Examiner rejects claim 1-10 under 35 U.S.C. §112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly the subject matter which Applicant regards as the invention. More specifically, the Examiner objects to Applicant's use of the term "protein content" in the claims.

In response, in an effort to advance prosecution, Applicants have amended claims 1 and 3 to replace "protein content" with "total amount of protein." Accordingly, Applicants respectfully request that the Examiner withdraw his rejection of claims 1-10 under 35 U.S.C. §112, second paragraph.

Rejection of Claims 1-4, 7 & 10 Under 35 U.S.C. §102

In paragraph 2 of page 4, the Examiner rejects claim 1-4, 7 & 10 under 35 U.S.C. §102 as allegedly anticipated by U.S. Patent No. 5,317,084 to Tomita et al. ("Tomita") (wherein the ionic strength is evidenced by Wikipedia.

Applicants respectfully disagree. Currently amended claim 1 requires, among other things, the use of a cationic exchange resin and washing the resin with an alkaline wash solution. Furthermore, claim 1 requires a minimum concentration of the alkaline solution of 0.05 N (mole/l), which is necessarily strongly alkaline, (*i.e.*, having a pH above about 12) . None of these limitations are taught or suggested by Tomita or any of the other prior art of record. It should be appreciated that the claimed methods and processes lead to the important and unexpected advantage of permitting desorption of the desired peptide from the resin using an eluent of low ionic strength or even demineralised water. In other words, the claimed methods and processes avoid high salt solutions and subsequent desalting, which are laborious and environmentally undesirable processes, while they are necessary in the process of Tomita. (see e.g. col. 5, line 10 ff.).

No such steps of the claimed methods or processes are disclosed or suggested in Tomita. For example, and not by way of limitation, Examples 1 and 2 of Tomita et al. describe the use of a cation exchange resin, but no alkaline, let alone a strongly alkaline, washing step is included. The peptide is then desorbed by Tomita et al., using a concentrated salt solution (2M ammonium acetate), followed by desalting using large volumes of water (5 liters for 1.4 g peptide product).

Tomita and the other cited prior art of record do not teach or suggest the use of the distinguishing steps of the claimed methods and processes, as explained, nor does Tomita or the other prior art of record achieve the advantages that are achieved by the present invention. For each of these reasons independently, Applicants respectfully request that the Examiner withdraw his rejection of claims 1-4, 7 and 10 under 35 U.S.C. §102.

Rejection of Claims 1, 5, 6, 8 and 9 Under 35 U.S.C. §103

In paragraph 2 of page 6 of the Office Action and paragraph 2 of page 8 of the Office Action, the Examiner rejected claims 1, 5 and 6 and 1, 8 and 9 respectively under 35 U.S.C. § 103(a) in view of DeFrees et al. (US2008/027487) ("DeFrees") and Jensen et al. (US2007/0104764 A1) ("Jensen").

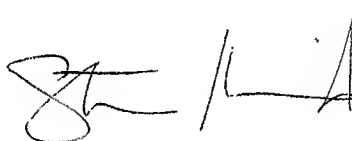
Applicants note that DeFrees has a priority and filing date of 2007. The present application has an effective priority and date of July 17, 2003. Accordingly, the DeFrees reference is not prior art to the present application. Accordingly, Applicants respectfully request withdrawal of the rejection of claims 1, 5 and 6 based on DeFrees and removal of DeFrees as a prior art reference.

Similarly, Jensen has a Danish priority date of September 2003 and a PCT/US filing date of September 2004. The present application has an effective priority and date of July 17, 2003. Accordingly, Jensen is not prior art to the present application. Accordingly, Applicants respectfully request withdrawal of the rejection of claims 1, 8 and 9 based on Jensen and removal of Jensen as a prior art reference. Furthermore, it should be appreciated that Jensen discloses plants as expression systems for recombinant proteins, while claim 8 and 9 refer to plants as the (native) source of the starting proteins.

It is respectfully submitted that all of the Examiner's objections have been successfully traversed and that the application is now in order for allowance. Accordingly, reconsideration of the application and allowance thereof is courteously solicited.

The Director is authorized to charge a one-month extension of time fee in the amount of \$130.00, as well as any additional fee(s) or any underpayment of fee(s), or to credit any overpayments to **Deposit Account Number 50-2638**. Please ensure that Attorney Docket Number 072998-014000 is referred to when charging any payments or credits for this case.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'SH' followed by a stylized 'LA'.

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